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REMARKS

Claims 1-55 remain pending. No new claims have been added. Claims 1, 24-27, 36-37 and 40 have been amended. New claims 50-55 have been added. No claims have been canceled. All other claims remain the same. Reconsideration of the claims as presented herein is respectfully requested.

The claims are amended as follows and as detailed in the attached "Amendments to the Claims":

In line 1 of claim 1: delete the term "improved".

In line 1 of subsection c) of claim 1: replace "or" with -- and/or --.

In line 1 of subsection c) of claim 24: replace "or" with -- and/or --.

In line 1 of subsection c) of claim 25: replace "or" with -- and/or --.

In line 1 of subsection c) of claim 26: replace "or" with -- and/or --.

In line 1 of subsection c) of claim 27: replace "or" with -- and/or --.

In line 2 of claim 37: insert -- and/ -- before "or".

In line 2 of claim 40: insert -- and/ -- before "or water".

Amend claim 36 to include the subject matter of claim 25 and remove dependency from claims 26 and 27.

Add new claims 50-55 to cover the subject matter removed, by amendment of dependencies, from claim 36.

Applicants note that the status of claim 36, which depends from claim 25, 26 or 27 and which requires the presence of the PVP-VA polymer, is not indicated in the Office Action. Applicants assume that the claim would be allowable if rewritten in independent form. Accordingly, claim 36 has been amended to include the subject matter of claim 25 and remove the dependency to claims 26 and 27. In addition, new claims 50-52 and 53-55 are presented to cover the subject matter of claim 36 in combination with claims 26, 37, 38 and claims 27, 37, 38, respectively.

Claims 1-23 stand rejected under 35 U.S.C. §112, 2nd para. as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner indicated lack of clarity regarding the term "improved" in claim 1. Claims 2-23 depend either directly or indirectly from and include the subject matter of claim 1.

Applicants have amended claim 1 by deletion of the term "improved". Applicants respectfully submit that the rejection of claims 1-23 under 35 U.S.C. §112, 2nd para. has been overcome and request that it be withdrawn.

Applicants note that claims 1, 24-27, 37 and 40 have also been amended to include the term "and/or" in place of the term "or" in subsection c). Applicants submit that no new subject matter has been added by way of amendment. As regards the external coat, the term "and/or" is clearly supported by the specification as originally filed and by the issued patent (Col. 5, lines 35-39).

Claims 24-35 and 37-49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Savastano et al. (U.S. 5,681,584) [in view of] Herbig et al. (U.S. 5,609,590). Insofar as it may apply to the present claims, this rejection is respectfully traversed.

Claims 24-27 are independent claims. Claims 28-49 depend directly or indirectly from those claims and include the subject matter thereof. In brief, claims 24-27 require a multi-layered osmotic device comprising a drug-containing core, a semipermeable membrane surrounding the core and having at least one preformed passageway there through, an inert, completely erodible and/or water soluble polymer coat surrounding the semipermeable membrane, and a drug-containing coat. As noted in the specification, the instant osmotic device is capable of providing a range of different controlled release profiles. It does so even in the absence of any coating, e.g. the delayed release coating of Savastano et al., between the semipermeable membrane and the core. The instant device delivers drug substantially throughout the gastrointestinal (GI) tract (at least from the stomach and farther downstream thereof) by first delivering drug from the external coat and then delivering drug from the core of the device to the upper GI tract on down. By virtue of its design, the instant device is easier to manufacture and more versatile than that of Savastano et al. The present device does not require cooperation of two different coatings to provide controlled release of drug from the core.

On the other hand, the device of Savastano et al. requires an additional delayed release jacket between the semipermeable membrane and the core even though Savastano et al.'s device already requires an external enteric coat. The internal delay jacket is required because the enteric coat does not sufficiently delay the release of drug from the core. In other words, the device of Savastano et al. requires cooperation of the delay jacket and the enteric coating in order to function as intended. Their device is adapted to deliver drug (from the core) to a particular

region of the GI tract, in particular the lower end of the GI tract. Applicants submit that Savastano et al. would not be motivated to remove the delay jacket from their device, since its presence is required by virtue of it having to cooperate with the enteric coat (Col. 11, lines 30-31) to control release of drug from the core. Moreover, even in the absence of the enteric coat, the delay jacket continues to affect the rate of release of drug from the core (Col. 11, line 44 to Col. 12, line 5). Elimination of the delay jacket from the core would result in an osmotic device behaving differently than as intended by Savastano et al.

The combination of the disclosures of Herbig et al. and Savastano et al. does not provide what Savastano et al. on its own is missing. Herbig et al. disclose bursting drug delivery devices. Their devices burst and provide a rapid release of drug after the internal osmotic pressure of the device has built up sufficiently to catastrophically rupture the membrane or seal of the device. Contrary to the instant device, the device of Herbig et al. does not provide a controlled release of drug from the core of the device while the membrane surrounding the core is physically intact. When properly combined in the absence of hind sight reconstruction, a prophetic osmotic device resulting from the proposed combination of disclosures would comprise: a core surrounded by a delay jacket that is then surrounded by an optionally rupturing semipermeable membrane, and then an enteric coating. The device would also include a pH sensitive coating external to the semipermeable coating; however, its location with respect to the enteric coating could not be determined in view of the combined disclosures. The combination device may or may not provide a controlled release of drug, since the device of Herbig et al. includes a semipermeable membrane that ruptures but that of Savastano et al. does not. Moreover, the device might or might not provide an initial release of drug from an external drug-containing coat. The combination of Savastano et al. and Herbig et al. fails to disclose or suggest an osmotic device requiring all of the elements as claimed herein; therefore, the combination fails to render the claimed invention obvious.

Accordingly, Applicants respectfully submit that the rejection of claims 24-35 and 37-49 under 35 U.S.C. §103(a) as being unpatentable over Savastano et al. (U.S. 5,681,584) [in view of] Herbig et al. (U.S. 5,609,590) has been overcome and request that it be withdrawn.

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Applicants have made a diligent effort to advance the prosecution of the application by amending the claims and presenting supporting arguments. In view of the above, applicants submit that the claims are in form for allowance. An early notice of allowance thereof is requested.

Respectfully submitted,

Date: 4/4/3

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